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Re:	09/866,030	**CC:**	

Applicants: Bhullar
Application: 09/866030
Filed: 05-25-2001
Ref. No.: WP 19301 US

Attachments:

- Transmittal Form (1pp)
- Reply Brief of Bhullar et al. (28 pp)
- Fax Transmittal Sheet (1pp)

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TRANSMITTAL FORM

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Total Number of Pages In This Submission	30

Application Number	09/866,030
Filing Date	May 25, 2001
First Named Inventor	Bhullar
Art Unit	1743
Examiner Name	Siefke, Samuel P.
Attorney Docket Number	19301 US

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
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Firm Name	The Law Office of Jill L. Woodburn, LLC		
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Date	August 16, 2007	Reg. No.	39874

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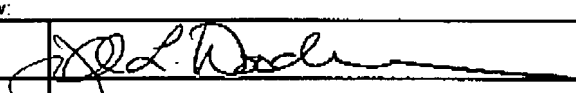
Signature			
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(1) IDENTIFICATION PAGE

Docket No. 19301 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bhullar et al.

Application No.:	09/866,030	Group No.: 1743
Filed:	May 25, 2001	Examiner: Siefke, Samuel P.

For: Biosensor

REPLY BRIEF OF BHULLAR ET AL.

(2) STATUS OF THE CLAIMS

The captioned application was filed as Serial No. 09/866,030 on May 25, 2001. The 19 claims in that initial filing were subjected to an election/restriction requirement: Group I – claims 1-15 drawn to a biosensor; Group II – claims 16-19 drawn to a method of making a biosensor. Group I, claims 1-15 were provisionally elected for prosecution. Claims 16-19 were withdrawn from consideration and subsequently cancelled. In response to the Office Action mailed September 22, 2003 and Reply to Notice of Non-Compliant Amendment mailed March 17, 2004, dependent claim 9 was cancelled and independent claim 20 and dependent claims 21-23 drawn to a biosensor were added. In response to the Office Action mailed January 11, 2005, independent claims 1, 8 and 20 along with dependent claims 2-5 and 7, were cancelled and independent claims 24-26 drawn to a biosensor were added. Claims 6, 10-15 and 21-26 are currently rejected and are being appealed.

(C) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejection of claim Claims 6, 10-15, and 21-26 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim Claims 6, 10-15 and 21-26 under 35 U.S.C. 102(b) as being anticipated by Nankai (USPN 5,120,420).

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(D) ARGUMENT

This paper is a Reply Brief in Response to the Examiner's Answer of Appellants' Brief of Bhullar et al. mailed on June 18, 2007.

Discussion of 112 Rejections

Regarding the Examiner's statements directed to the 112 rejections, Appellants have the following comments.

First, Appellants' respectfully traverse the Examiner's disagreement with the citing of In re Wakefield in the Appellants' Arguments. In re Wakefield 422 F.2d 897 was not cited in Appellants' Brief, but rather in the Reply to the Final Office Action mailed on August 26, 2005. At that time, given the Examiner's request for features to appear in the claims, Appellants stand by the citing of In re Wakefield, for the proposition that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification.

Second, the Examiner has again spelled out a specific three-point test for analysis of definiteness of claim language. Specifically, the Examiner states that "The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time the invention was made."

Appellants' will specifically point out the deficiencies in the rejection using the specifics of that three point test, except in those instances where the language rejected by the Examiner does not appear in the claim.

Also the Examiner stated that "Numerous examples were made to try to aid the Applicant in restructuring the claim language but the attempts failed." That statement is traversed, and will be addressed with respect to each of the rejections.

1. The Examiner has asserted that Claim 24 is confusing with respect to the recitation of "a support having first and second ends".

(A) The content of the particular application disclosure defines an embodiment of the substrate as having "first and second ends" (page 1 lines 14-15). Still further, the specification describes the substrate of Figures 2 and 3 including a "first surface 24 . . . a second surface 26 . . . opposite first and second ends 28, 30 and opposite edges 32, 34 extending between the first and second ends 28, 30" (page 3 lines 12-15). Figures 1A and 2 illustrate opposite first and second ends 28, 30 and the substrate 12.

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would not interpret the claims differently than that the content of the particular application disclosure.

As such, it is submitted that the language of the claim is such that a person of ordinary skill in the art could sufficiently interpret the metes and bounds of the claim so as to understand how to avoid infringement. As such, a rejection of the claim under 35 U.S.C. 112, second paragraph, is not appropriate.

Regarding the Examiner's statement that "Numerous examples were made to try to aid the Applicant in restructuring the claim language but the attempts failed", it is of note that the Examiner never rejected the claim language "a support substrate having first and second ends", as being unclear, which appeared in now cancelled claim 1. See, Office Actions dated 7/3/2003; 9/22/2003; 8/10/2004; 1/11/2005. Only in the Office

Action of 5/26/2005 did the Examiner first raise a rejection regarding the claim language "a support having first and second ends" of then new claim 24.

In the subsequent Office Action of 11/18/2005, no examples were made by the Examiner to try to aid the Applicant in restructuring the claim language. As such, Appellant disputes this "numerous examples" statement with respect to this aspect of the rejection.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the specification and claims use the term "first and second ends" in a manner consistent with their ordinary meaning given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made and therefore meet the requirements under Section 112, second paragraph.

2. The Examiner has asserted further that Claim 24 is unclear with respect to the phrase "electrode array". Specifically, the Examiner asserts that it is unclear to define two pairs of electrodes and call it an array.

(A) The content of the particular application defines an embodiment of the substrate as supporting two spaced-apart electrode arrays (page 2 lines 20-21). Further, it teaches that "electrodes 14, 16, 18 cooperate with one another to define first and second electrode arrays 76, 78 and leads 80 that extend away from the first and second arrays 76, 78" (page 4 lines 19-21). Figures 1B and 2 illustrate electrode arrays 66, 78.

(B) There has been nothing cited in the prior art by the Examiner that inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that the content of the particular application disclosure.

It is submitted that "electrode arrays" are described both in the text of the application as well as the drawings. It is submitted that the use of the phrase "electrode arrays" in

the text of the specification as well as by reference in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

Regarding the Examiner's assertion that "Numerous examples were made to try to aid the Applicant in restructuring the claim language but the attempts failed", the Examiner did not reject the claim language "electrode arrays", as being unclear, which appeared in now cancelled claim 1. See, Office Actions dated 7/3/2003; 9/22/2003; 8/10/2004; 1/11/2005. Only in the Office Action of 5/26/2005 did the Examiner first raise a rejection regarding the claim language "electrode arrays" of then new claim 24.

In the subsequent Office Action of 11/18/2005, no examples were made by the Examiner to try to aid the Applicant in restructuring the claim language. As such, Appellant disputes this "numerous examples" statement with respect to this aspect of the rejection.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that, the phrase "electrode arrays" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

3. The Examiner has asserted that Claim 24 is unclear with respect to the recitation of "a spacer having individual members".

(A) The content of the particular application defines an embodiment of the spacer substrate 20 as having a first member 40 and second and third members 42, 44 spaced-apart from the first member 40 (page 4 lines 28-30). See Fig. 2. Additionally, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (page 5 lines 3-5).

(B) There has been nothing cited in the prior art by the Examiner that inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that of the content of the particular application disclosure.

It is submitted that "a spacer having individual members" is described both in the text of the application as well as the drawings. It is submitted that the use of the phrase "a spacer having individual members" in the text of the specification as well as by reference in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

The 112, second paragraph rejection was first raised by the Examiner regarding the phrase "a spacer having individual members" in the 5/26/05 Office Action. In this instance, the Examiner recommended claiming "2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers".

As discussed above, there is support in the specification and Figure 2 for first, second and third members 40, 42, 44. Accordingly, support exists in the specification and drawings for the term "members". Moreover, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (page 5 lines 3-5). Accordingly, support exists in the specification and drawings for arrays to be positioned between three members. A limitation listing an exact number of 2 spacers (proposed by the Examiner), which is less than the number of members disclosed in the specification, is not necessary for purposes of 35 U.S.C. 112, second paragraph. As such, the restructuring of the claim language as proposed by the Examiner was unwarranted.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "a spacer having individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

4. The Examiner has asserted that Claim 24 is unclear with respect to the phrase "a cover cooperating with the support to define a capillary channel extending between the individual members".

(A) The content of the particular application defines an embodiment of a cover, a support, and first, second and third members 40, 42, 44. Support exists in the specification (page 1 lines 18-19 and 27-28) and drawings (Figures 1A and 1B) for a channel defined by the cover and the support. Support also exists in the specification (page 6 lines 6-11) and drawings (Figures 1A and 1B) for the phrase "a capillary channel extending between the individual members".

(B) There has been nothing cited in the prior art by the Examiner that inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that of the content of the particular application disclosure.

It is submitted that "a cover cooperating with the support to define a capillary channel extending between the individual members" is described both in the text of the application as well as the drawings. It is submitted that the use of the phrase "a cover cooperating with the support to define a capillary channel extending between the individual members" in the text of the specification as well as by reference in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

The 112, second paragraph rejection was first raised by the Examiner regarding the phrase "a cover cooperating with the support to define a capillary channel extending between the individual members" in the 5/26/05 Office Action. In this instance, the Examiner stated that "The cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this".

The channel is defined by the cover and support and extends "between the individual members". Thus, not only are all of the terms of the phrase definite, but the phrase

also shows the communication between each object. As such, the restructuring of the claim language as proposed by the Examiner was unwarranted.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that Claim 24 sufficiently defines the metes and bounds of the channel. The phrase "a cover cooperating with support to define a capillary channel extending between the individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

5. The Examiner has asserted that Claim 24 is unclear with respect to the phrase "the channel having opposite ends". The Examiner has asserted that "It is unclear and indefinite to claim a channel having opposite ends. Where does a channel end on the support?"

The Examiner first raised this point in the Office Action of 05/26/2005. In response to the Examiner's concerns at that time, the claim was amended to recite the channel having "spaced-apart first and second opposite outlets". In response to that amendment, the Examiner twice repeated the rejection of the claim being indefinite for having "opposite ends" (11/18/2005 and 6/18/2007).

As such, Applicants again state that Claim 24 **does not** recite a channel having opposite ends, but rather recites a channel having opposite outlets. It is submitted that the phrase "the channel having opposite outlets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

6. Examiner has asserted that Claim 24 is unclear with respect to the phrase "a concave inlet extending from the first end of the support and being positioned between opposite ends of the channel". The Examiner has asserted that it is unclear and indefinite to claim "a concave inlet extending from a first end, what first end? Where on the support?"

(A) The content of the particular application defines the term "concave inlet" (page 6 lines 1-2; page 10 lines 11-14 and Figure 1A). Specifically, Fig. 1A illustrates the sample inlet 84 having a concave shape.

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that of the content of the particular application disclosure.

Accordingly, the term "a concave inlet" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

As discussed above in point 1, it is submitted that the phrase "first end of the support" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

As discussed above in point 5, it is submitted that the phrase "opposite outlets of the channel" is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

As discussed above in point 4, it is submitted that the phrase "a cover cooperating with the support to define a capillary channel extending between the individual members" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

So, it follows that the phrase "a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel", is also definite for purposes of Section 112, second paragraph. As such, the positioning and orientation of the inlet with respect to support as well as the cover, members of the spacer, and channel is sufficiently defined.

It is submitted that the Examiner provided no example to try to aid the Applicant in restructuring the claim language in this regard. The Examiner, did however, ask the question, "The inlet is the channel?" It is submitted that the specification teaches an example at page 6 lines 1-2, "Referring now to Figs. 1A and 1B, the capillary channel 82 is generally linear in shape and includes a sample inlet 84 and spaced-apart ends 86. As such, the use of the term "inlet" with respect to a channel is in accordance with its ordinary meaning that is well understood by ordinary practitioners in the field of biosensors.

The Examiner also asks, then states "How is the inlet positioned between opposite ends? None of the figures show this". Again, attention is directed to Figs. 1A and Fig. 4. Where the capillary channel 82 is generally linear in shape and includes a sample inlet 84 and spaced-apart ends 86, wherein the inlet 84 is positioned between ends 86. Also illustrating this construction, Figure 2 is the exploded assembly view of the biosensor of Fig. 1.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

7. Examiner has asserted that Claim 24 is unclear with respect to the phrase "each electrode array being positioned in the channel adjacent to one of the opposing ends".

Regarding the term "electrode arrays", as discussed above in point 2,

(A) The content of the particular application defines the substrate as supporting two spaced-apart electrode arrays (page 2 lines 20-21). Further, it teaches that "electrodes 14, 16, 18 cooperate with one another to define first and second electrode arrays 76, 78 and leads 80 that extend away from the first and second arrays 76, 78" (page 4 lines 19-21). The drawings illustrate electrode arrays 76, 78 in Figures 1B and 2.

(B) There has been nothing cited in the prior art by the Examiner that inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that the content of the particular application disclosure.

As such, "electrode arrays" are described both in the text of the application as well as the drawings. It is submitted that the use of the phrase "electrode arrays" in the text of the specification as well as by reference in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

Next, regarding the phrase "each electrode array being positioned in the channel adjacent to one of the opposing outlets":

(A) The content of the particular application defines in the text of the claim, the specification, and drawings that each electrode array is positioned in the channel adjacent to one of the opposing outlets of the channel (page 1 lines 27-29; page 2 lines 6-7; and Figures 1A and 4).

(B) There has been nothing cited in the prior art by the Examiner that inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that the content of the particular application disclosure.

As such, the phrase "each electrode array being positioned in the channel adjacent to one of the opposing outlets" is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

It is submitted that the Examiner provided no example to try to aid the Applicant in restructuring the claim language in this regard. The Examiner did, however, reject the phrase "opposing ends" and made the question, then comments, "What opposing ends? Adjacent to what? The electrode arrays are just two electrodes connected to each other to make a couple of pair of electrodes not an array."

First, as discussed above in point 5, Claim 24 does not recite opposing ends of a channel, but rather opposing outlets. As such, the question "What opposing ends?" is irrelevant. The question, "Adjacent to what?" is answered in the phrase itself "adjacent to one of the opposing outlets".

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "each electrode array being positioned in the channel adjacent to one of the opposing outlets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Claim 24 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding Claim 25:

1. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "a support having first edge". Specifically, the Examiner has asserted that it is unclear to define an edge on a support that has six sides.

(A) The content of the particular application disclosure defines an embodiment of a substrate 12 that includes opposite edges 32, 34 extending between the first and second ends 28, 30. Figures 1A and 2 also illustrate edges 32, 34 of the support.

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would not interpret the claims differently than that the content of the particular application disclosure.

As such, it is submitted that the specification and claims use the term "first edge" in a manner consistent with its ordinary meaning given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made and therefore meet the requirements under Section 112, second paragraph.

It is of note that the Examiner provided no example to try to aid the Applicant in restructuring the claim language in this regard. As such, Appellant disputes this "numerous examples" statement with respect to this aspect of the rejection.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "a support having first edge" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

2. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "first and second electrode sets positioned on the support spaced apart from one another".

(A) The content of the particular application disclosure defines an embodiment of the substrate as having first and second electrode sets positioned on

the support spaced apart from one another (page 1 lines 23-26; page 3 lines 1-3 and 26-27; page 4 lines 11-15; page 9 lines 4-6; and Figures 2-4).

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would not interpret the claims differently than that the content of the particular application disclosure.

Thus, it is submitted that all of the terms of the phrase "first and second electrode sets positioned on the support spaced apart from one another" are definite.

The Examiner requested details on where on the support and the orientation of the electrodes. Claim 25 does in fact recite that the electrode sets are positioned on the support spaced apart from one another. As such, it is submitted that Claim 25 sufficiently demonstrates communication between each object in a clear and concise manner and the additional details requested by the Examiner were unwarranted.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the use of the phrase "first and second electrode sets positioned on the support spaced apart from one another" is sufficient to meet the requirements under Section 112, second paragraph.

3. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "a spacer having individual members".

(A) The content of the particular application defines the spacer substrate 20 as having a first member 40 and second and third members 42, 44 spaced-apart from the first member 40 (page 4 lines 28-30). See Fig. 2. Additionally, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (page 5 lines 3-5).

(B) There has been nothing cited in the prior art by the Examiner that inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would interpret the claims differently than that of the content of the particular application disclosure.

So, the phrase "a spacer having individual members" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

The 112, second paragraph rejection was first raised by the Examiner regarding the phrase "a spacer having individual members" in the 5/26/05 Office Action. In this instance, the Examiner recommended claiming "2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers". As discussed above, there is support in the specification and Figure 2 for first, second and third members 40, 42, 44. Accordingly, support exists in the specification and drawings for the term "members". A limitation listing an exact number of 2 spacers (proposed by the Examiner), which is less than the number of members disclosed in the specification, is not necessary for purposes of 35 U.S.C. 112, second paragraph. As such, the restructuring of the claim language as proposed by the Examiner was unwarranted.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "a spacer having individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

4. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "a cover having a second edge and extending across the first and second electrode sets".

Again, Claim 25 ***does not*** recite the phrase asserted by the Examiner. Instead, the Claim 25 recites "a cover having a second edge, the cover extending across the first and second electrode sets". As such, the Examiner's assertion "it is more than likely that the edge is not extended across the first and second electrode, it would be a plane of the cover and not an edge", is moot.

Further:

(A) The content of the particular application disclosure defines an embodiment of the cover 22 with edges 66, 68, extending between the first and second ends 62, 64. See, Figs. 1A and 2. Further, Fig. 1B, an enlarged perspective view of Fig 1A, away shows how cover extends across an electrode set. Fig. 2, the exploded assembly view shows how cover 22 extends across two electrode sets formed from electrodes 14, 16, 18.

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would not interpret the claims differently than that the content of the particular application disclosure

As such, the phrase "a cover having a second edge" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

It is of note that the Examiner provided no example to try to aid the Applicant in restructuring the claim language in this regard. As such, Appellant disputes this "numerous examples" statement with respect to this aspect of the rejection.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "a cover having a second edge, the cover extending across the first and second electrode sets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

5. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "the cover cooperating with support to define a generally linear capillary channel extending between the individual members".

(A) The content of the particular application disclosure defines an embodiment of a generally linear capillary channel (page 1 line 28). Further, the specification teaches at page 6 lines 1-2, "Referring now to Figs. 1A and 1B, the capillary channel 82 is generally linear in shape and includes a sample inlet 84 and spaced-apart ends 86". Further, at page 6 lines 7-9, "Channel is also defined by inner edge 50 of first member 40 of the spacer substrate 20 and the first edges 54 of the second and third members 42, 44. See, Fig. 4".

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would not interpret the claims differently than that the content of the particular application disclosure

So, the term "generally linear channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

The 112, second paragraph rejection was first raised by the Examiner regarding the phrase "a cover cooperating with the support to define a generally liner capillary channel extending between the individual members" in the 5/26/05 Office Action. In this instance, the Examiner stated that "The cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this. A generally linear channel is unclear and indefinite".

It is submitted that Claim 25 sufficiently defines the metes and bounds of the channel. The channel is defined by the cover and support and extends "between the individual members". Thus, not only are all of the terms of the phrase definite, but the phrase also shows the communication between each object. As such, the restructuring of the claim language as proposed by the Examiner was unwarranted.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "a cover cooperating with support to define a generally liner capillary channel extending between the individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

6. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "the channel having opposing first and second ends and an inlet aligned with the first edge of the support and the second edge of the cover".

Again, Claim 25 ***does not*** recite the phrase asserted by the Examiner. Instead, the Claim 25 recites "the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover".

The Examiner asks, "How does a channel have opposing first and second ends if it is not a totally closed channel, sounds more like a chamber, it is unclear and indefinite." As Claim 25 ***does not*** recite "first and second ends", but rather "first and second outlets" the Examiner's question and accompanying assertion is moot.

Next, the Examiner has asserted that "First edge of the support and the second edge of the cover is unclear and indefinite, where are the spacers in this orientation?" As

discussed above in points 1 and 4, the phrases "first edge of the support" and the "second edge of the cover" are fully supported by the specification and drawings and as such their respective meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding the location of the spacer, Claim 25 recites that the cover cooperates with the support to define a generally linear capillary channel extending between the individual members. As such, it is submitted that Claim 25 sufficiently demonstrates communication between each object in a clear and concise manner.

It is of note that the Examiner provided no example to try to aid the Applicant in restructuring the claim language in this regard. As such, Appellant disputes this "numerous examples" statement with respect to this aspect of the rejection.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover" is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

7. The Examiner has questioned to what the phrase "between the ends of the channel" in claim 25 is referring.

As discussed above in point 6, Claim 25 ***does not*** recite the phrase asserted by the Examiner. Instead, Claim 25 recites that the channel has "opposing first and second outlets". As such, the Examiner's question is moot.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase "between the outlets of the channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

8. The Examiner has asserted that the phrase "and between the first and second electrode sets" is unclear and indefinite. Specifically, the Examiner has asserted that "The biosensor needs to show communication between each object in a clear and concise manner in which one of ordinary skill in the art would be able to have a clear understanding of the invention.

(A) The content of the particular application disclosure defines an embodiment of the substrate as having first and second electrode sets positioned on the support spaced apart from one another (page 1 lines 23-26; page 3 lines 1-3 and 26-27; page 4 lines 11-15; page 9 lines 4-6; and Figures 2-4).

(B) There has been nothing cited in the prior art by the Examiner that is inconsistent with the claim language or the content of the particular application disclosure.

(C) There is nothing presented in the record to demonstrate why one possessing the ordinary skill in the pertinent art at the time the invention was made would not interpret the claims differently than that the content of the particular application disclosure

To address the communication aspect of the rejection, Applicant will repeat the explanation provided in the previous Brief. Claim 25 recites "first and second electrode sets positioned on the support spaced-apart from one another", which satisfies communication between the electrode sets and the substrate. Next Claim 25 recites a cover "extending across the first and second electrode sets", satisfying communication between the electrode sets and the cover. Still further, Claim 25 recites an inlet to the channel positioned "between the first and second electrode sets", satisfying communication between the electrode sets and the channel. As discussed above, the channel itself is defined by the cover and support and extends between members of the spacer. Accordingly, it is submitted that the electrode sets are defined by Claim 25 with reference to each of the elements – substrate, cover, and spacer - of the claim.

As such, the phrase "between the first and second electrode sets" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary

practitioners in the field of biosensors for purposes under Section 112, second paragraph.

In light of the above as well as remarks set forth in Appellants' Appeal Brief, it is submitted that the phrase and "between the first and second electrode sets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Claim 25 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding Claim 26:

The Examiner has rejected Claim 26 as having the same problems as mentioned in Claim 24 and Claim 25. The Examiner asserts only that it is entirely unclear and indefinite as a whole.

To the extent that the rejection overlaps claims 24 and 25, it is submitted that the arguments made above with respect to Claims 24 and 25 apply to Claim 26.

Additionally, it is noted that Claim 26 recites a channel having "spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members, each electrode array being positioned in the channel adjacent to one of the opposite outlets". In light of the above discussion with reference to Claims 24 and 25, it is submitted that Claim 26 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Accordingly, Claims 24-26 are sufficiently definite for purposes under Section 112, second paragraph. Claim 6 depends from Claim 24, claims 10-15 depend from Claim 25, and claims 21-23 depend from Claim 26.

Appellant respectfully contends that the claims of the present invention comply fully with the requirements of 35 U.S.C. 112, second paragraph. Reversal of the rejection based on that statutory section is requested.

Discussion of 102(b) Rejections

Claims 6, 10-15, and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al. (USPN 5,120,420).

It is of note that the Final Office Action of 11/18/2005, was the only Office Action rejecting Claims 6, 10-15, and 21-26 under 35 U.S.C. 102(b) as being anticipated by Nankai et al. (USPN 5,120,420). In that Action, the Examiner did not direct Appellants' direction to Figure 10. As such, Appellants' arguments were not tailored to address the differences between that Figure and the pending claims because Appellants had no notice of this aspect of the rejection, which the Examiner has impermissibly raised de novo in this Appeal. Nevertheless, the following discussion will be directed to Nankai in its entirety, including Figures 10 and 12.

Appellants' do not dispute the Examiner's current statement that Nankai shows two separate individual spacers 7 and 7' in Figure 10. Nankai describes that "the spacer is divided into two parts 7 and 7' and these parts may be used as the spacer 8, and the introducing port 10 and the discharge port 11". Col. 7 lines 57-61. The channel of the spacer 8 is strictly linear, extending between ports 10, 11.

A review of Figure 10, however, indicates that it lacks a biosensor comprising "a capillary channel extending between the individual members, the channel having opposing outlets and a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel", as required by claim 24.

Further, Figure 10 lacks a biosensor comprising "a generally linear capillary channel extending between the individual members, the channel having opposing first and

second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel, and between the first and second electrode sets", as required by claim 25.

Still further, Figure 10 lacks a biosensor comprising a channel "extending between the three members and having an inlet positioned between the second and third members adjacent to the first end of the support and spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members", as required by claim 26.

Regarding claim 12, the statement that Nankai shows three individual members that separate the sample area above the electrodes 41, 42, and 43 is traversed.

It is submitted that Figure 12 of Nankai illustrates an embodiment having 3 pairs of electrodes on an insulating plate (1). A spacer (7) is adhered on the plate (1) and a cover (9) is adhered on the spacer (7). (Col. 5 lines 6-7 and Col. 8 lines 47-49). The spacer (7) of Figure 12 is not divided into parts. Rather it is single spacer partially cut off into a "comb-like" shape and the cut portions form a space (8). Three holes are formed in the cover (9) to provide discharge ports (11), (12), and (13). The introducing port (10) is at the end. Col. 8 lines 15-21.

Claim 24 recites "a capillary channel extending between the individual members, the channel having opposing outlets and a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel". None of the Figures (including Fig. 12) or text of Nankai et al. disclose a biosensor comprising a channel having opposing outlets and a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel. As such, Nankai et al. cannot be said to anticipate the biosensor of Claim 24.

Claim 25 recites "a generally linear capillary channel extending between the individual members, the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel, and between the first and second electrode sets". None of the Figures (including Fig. 12) or text of Nankai et al. disclose a generally linear capillary channel extending between the individual members, the channel having

opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel, and between the first and second electrode sets. As such, Nankai et al. cannot be said to anticipate the biosensor of Claim 25.

Claim 26 recites a channel "extending between the three members and having an inlet positioned between the second and third members adjacent to the first end of the support and spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members". None of the Figures (including Fig. 12) or text of Nankai et al. disclose a channel "extending between the three members and having an inlet positioned between the second and third members adjacent to the first end of the support and spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members. So, Nankai et al. cannot be said to anticipate the biosensor of Claim 26.

Reversal of the rejection of the claims under 35 U.S.C. 102(b) is requested because Nankai et al. fails to show each and every element recited by the claims.

Discussion of Dual Directional Flow

In the Examiner's Answer dated 06/18/2007, the Examiner made the statement that "This is the first time the Appellant brings up this duel directional flow". This statement is simply incorrect. Duel directional flow was explained in detail in response to the Examiner's rejection of claims 6, 10-15, and 21-26 under 35 U.S.C. 103(a) as being unpatentable over Nankai et al. (USPN 5,120,420) in the Office Action of 5/26/2005. That rejection was not repeated in the Office Action of 11/18/2005, it was assumed in part due to Appellants' Argument.

In part that argument was as follows:

> A key difference between the biosensors of Nankai et al. and Claims 24-26 relates to the flow pattern of the liquid sample within the biosensors. In that regard, the Examiner's attention is directed to each of the Figures of Nankai et al., where it is illustrated that a resulting

liquid flow pattern would be essentially forward moving. There is certainly no opposing dual-directional flow taught or suggested by Nankai et al. In fact, Nankai et al. teaches away from such an arrangement.

In that regard, the Examiner's attention is directed to Nankai et al. at column 5 lines 19-36:

When the introducing port at the tip of the glucose sensor constructed as described above is brought into contact with a glucose standard solution (200 mg/dl), which is a sample solution, the sample solution is introduced into the inside through the introducing port 10. In this case, the air in the space 8 is rapidly discharged through the discharge port 11 and at the same time, the space is filled up with the sample solution up to near the discharge port. As such, the sample solution rapidly spreads onto the electrode surface to fill up the space so that any remaining air bubbles are not noted.

This is believed to be because the sample solution would flow into *one direction* by providing the introducing port and the discharge port and due to the hydrophilic high molecular substance layer previously formed on the electrodes, wetting on the electrode surface would be improved so that the gas is smoothly exchanged with the liquid. (emphasis added)

As such, Nankai et al. teaches dual-directional flow as being worse than one-directional flow achieved by its disclosed biosensor configuration.

It is important to note that each of the biosensors of claims 24-26 is configured for and operate using opposing dual-directional flow of a liquid sample applied to its respective inlet."

Further, page 10 lines 18-21 of the specification as filed states that "In use, a user of biosensor places a finger having a blood collection incision against borders 38, 72 of

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notches 36, 70. Capillary forces pull a liquid blood sample flowing from the incision into the sample inlet 84 and through the capillary channel 82 across the reagents 88 and the arrays 76, 78". A review of Fig. 2 also illustrates this dual-directional flow.

As such, both the specification as filed and the Remarks of the Office Actions of 05/25/07 discussed in detail opposing dual directional flow.

In light of the above, Nankai et al.'s linear channel (Fig. 10), and comb-shaped channel (Fig. 12) teach away from the biosensors recited by Claims 24-26 and cannot be said to render the pending claims anticipated.

Conclusion

It is respectfully submitted that the claimed invention is not anticipated by Nankai et al. and further that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made.

In light of the above, reversal of the rejection of the claims under 35 U.S.C. 112, second paragraph and 35 U.S.C. 102(b) leading to allowance of the claims is requested

Respectfully submitted,

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